K082178
P. 1 of 1

TEPHA
MEDICAL DEVICES

OCT 30 2008

99 Hayden Avenue
Suite 360
Lexington, MA 02421
tel: (781) 357-1700
fax: (781) 357-1701

Section X
Summary of Safety and Effectiveness

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Tepha, Inc. is submitting the following summary of information respecting safety and effectiveness:

Trade Name:	TephaFLEX® Absorbable Suture
Sponsor:	Tepha, Inc. 99 Hayden Avenue, Suite 360 Lexington, MA 02421
Device Classification Name:	CFR §878.4494 Absorbable Poly(hydroxybutyrate) Surgical Suture
Classification:	According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.
Predicate Devices:	Tepha, Inc., TephaFLEX Absorbable Suture ENTrigue Surgical, Inc., BioElast™ Absorbable suture Ethicon, Inc., PDS II Absorbable Suture
Device Description:	TephaFLEX sutures are sterile, monofilament, absorbable surgical sutures constructed of poly-4-hydroxybutyrate. The TephaFLEX sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery, or ophthalmic surgery.
Safety and Performance:	Physical testing was performed on the TephaFLEX sutures to USP 28, including <861> Suture Diameter, <871> Suture Needle Attachment, <881> Tensile Strength. Animal testing was performed for conformance to ISO 10993 for biocompatibility and implant studies were conducted to demonstrate rates of tensile strength and mass loss.
Conclusion:	Based on the indications for use, technological characteristics, and safety and performance testing, the TephaFLEX Absorbable Suture has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tepha Medical Devices, Inc.
% Ms. Mary P. LeGraw
V.P. Regulatory Affairs
99 Hayden Avenue, Suite 360
Lexington, Massachussetts 02421

OCT 30 2008

Re: K082178
Trade/Device Name: TephaFLEX® Absorbable Suture
Regulation Number: 21 CFR 878.4494
Regulation Name: Absorbable poly (hydroxybutyrate) surgical suture produced by recombinant DNA technology.
Regulatory Class: II
Product Code: NWJ
Dated: July 31, 2008
Received: August 1, 2008

Dear Ms. LeGraw:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082178

Indications for Use

510(k) Number (if known): ~~Not Assigned~~

Device Name: TephaFLEX® Absorbable Suture

Indications for Use:

TephaFLEX absorbable sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

Prescription Use: X (21 CFR 801 Subpart D) AND/OR Over-The-Counter ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082178